FIG. 1

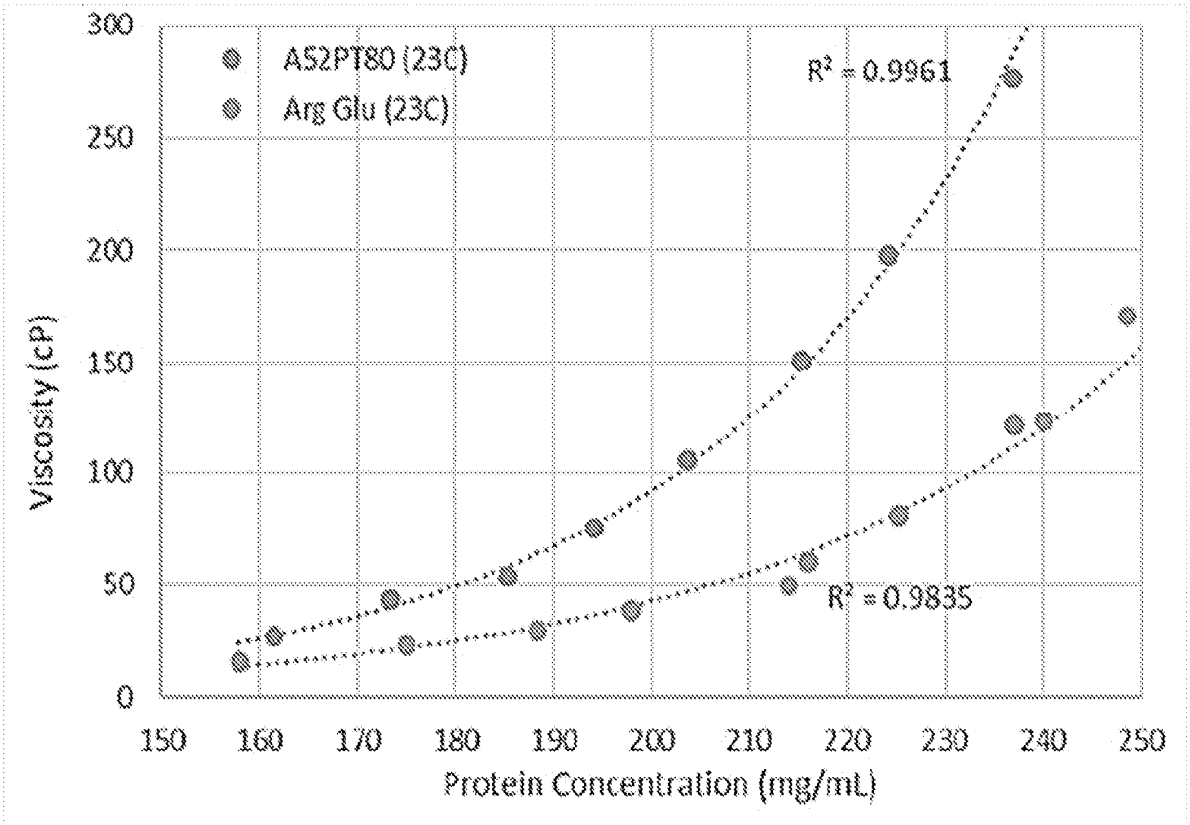

A52PT80 (23C)
Arg Glu (23C)
R² = 0.9961
R² = 0.9835
Viscosity (cP)
Protein Concentration (mg/mL)
300
250
200
150
100
50
0
150
160
170
180
190
200
210
220
230
240
250

FIG. 2

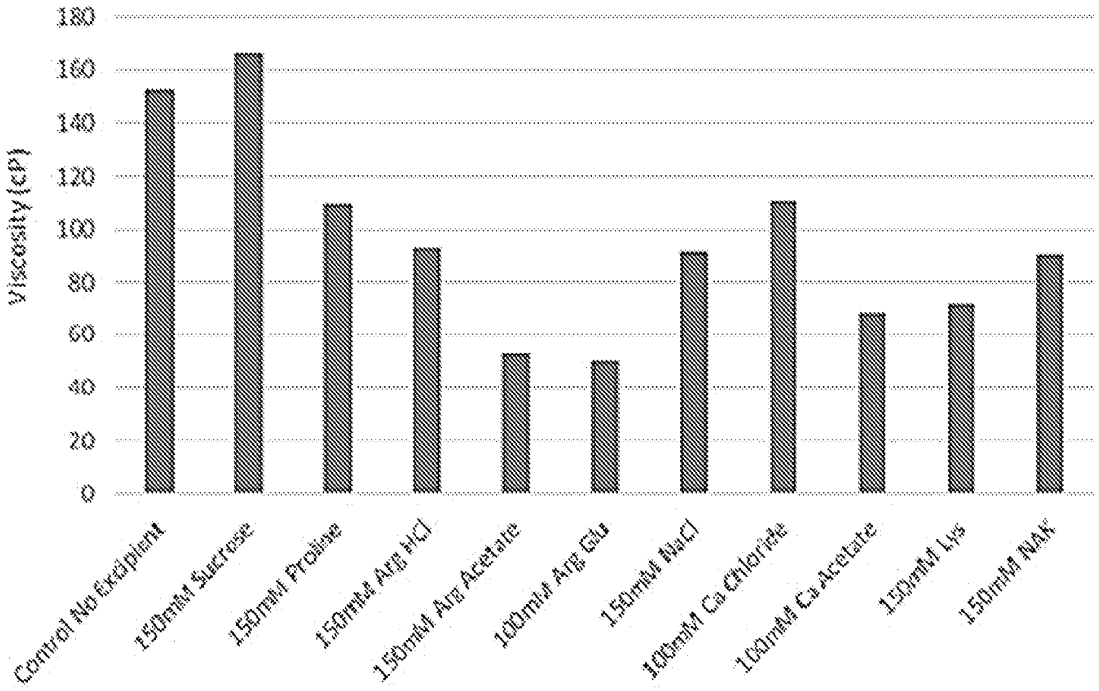

Viscosity (cP)
180
160
140
120
100
80
60
40
20
0
Control No Excipient
150mM Sucrose
150mM Proline
150mM Arg HCl
150mM Arg Acetate
100mM Arg Glu
150mM NaCl
100mM Ca Chloride
100mM Ca Acetate
150mM Lys
150mM NaK

FIG. 3

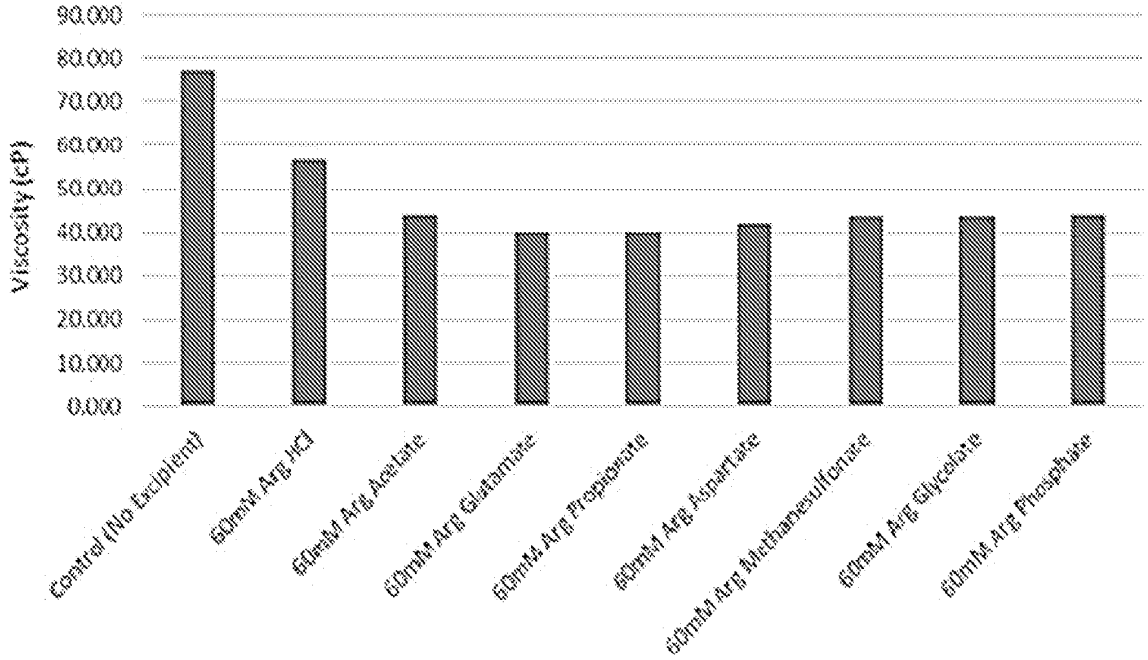

Viscosity (cP)
90.000
80.000
70.000
60.000
50.000
40.000
30.000
20.000
10.000
0.000
Control (No Excipient)
60mM Arg HCl
60mM Arg Acetate
60mM Arg Glutamate
60mM Arg Propionate
60mM Arg Aspartate
60mM Arg Methanesulfonate
60mM Arg Glycolate
60mM Arg Phosphate

FIG. 4

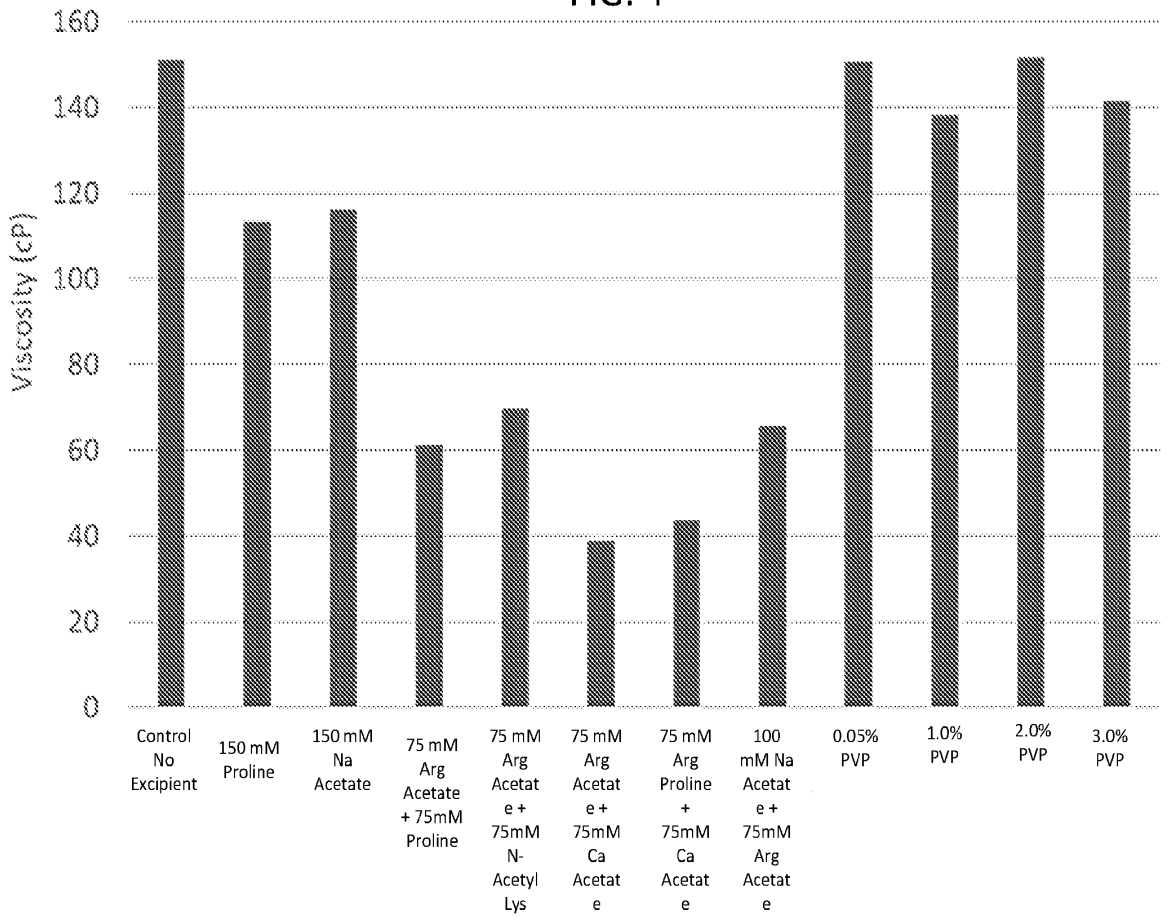

Viscosity (cP)
160
140
120
100
80
60
40
20
0
Control No Excipient
150 mM Proline
150 mM Na Acetate
75 mM Arg Acetate + 75mM Proline
75 mM Arg Acetate + 75mM N-Acetyl Lys
75 mM Arg Acetate + 75mM Ca Acetate
75 mM Arg Proline + 75mM Ca Acetate
100 mM Na Acetate + 75mM Arg Acetate
0.05% PVP
1.0% PVP
2.0% PVP
3.0% PVP

FIG. 5

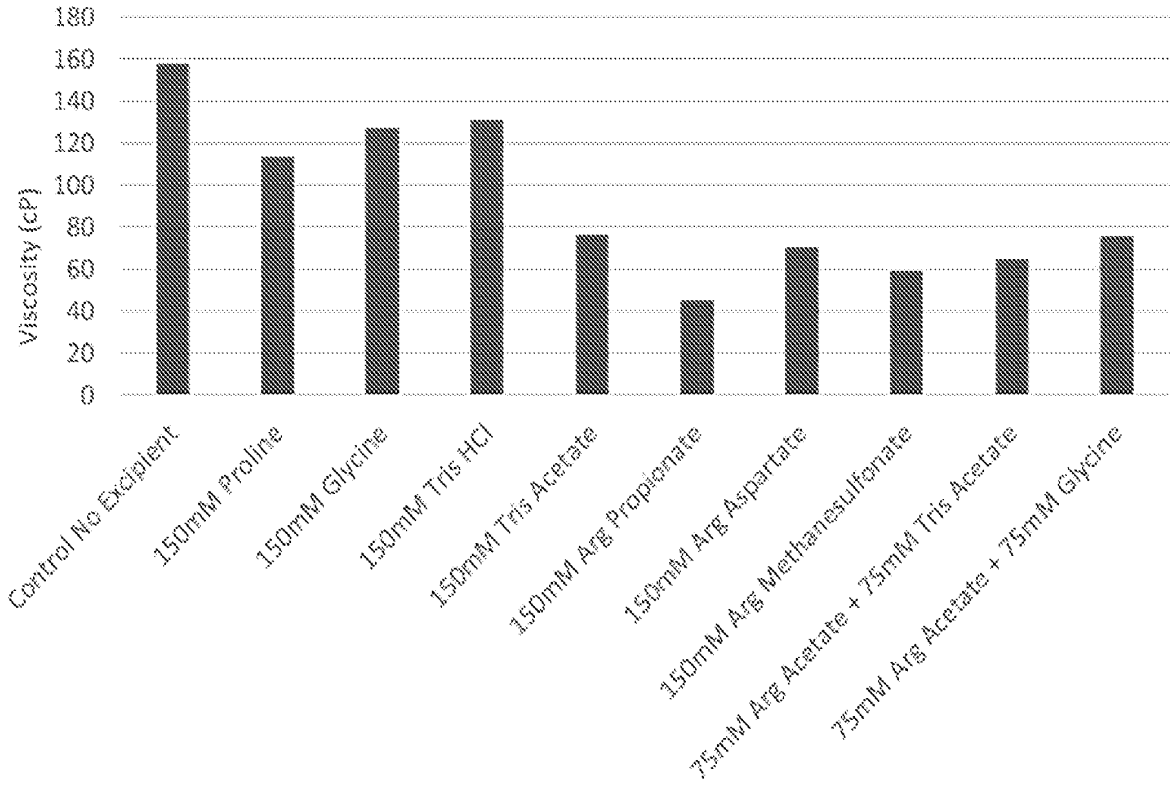

Viscosity (cP)
180
160
140
120
100
80
60
40
20
0
Control No Excipient
150mM Proline
150mM Glycine
150mM Tris HCl
150mM Tris Acetate
150mM Arg Propionate
150mM Arg Aspartate
150mM Arg Methanesulfonate
75mM Arg Acetate + 75mM Tris Acetate
75mM Arg Acetate + 75mM Glycine

FIG. 6

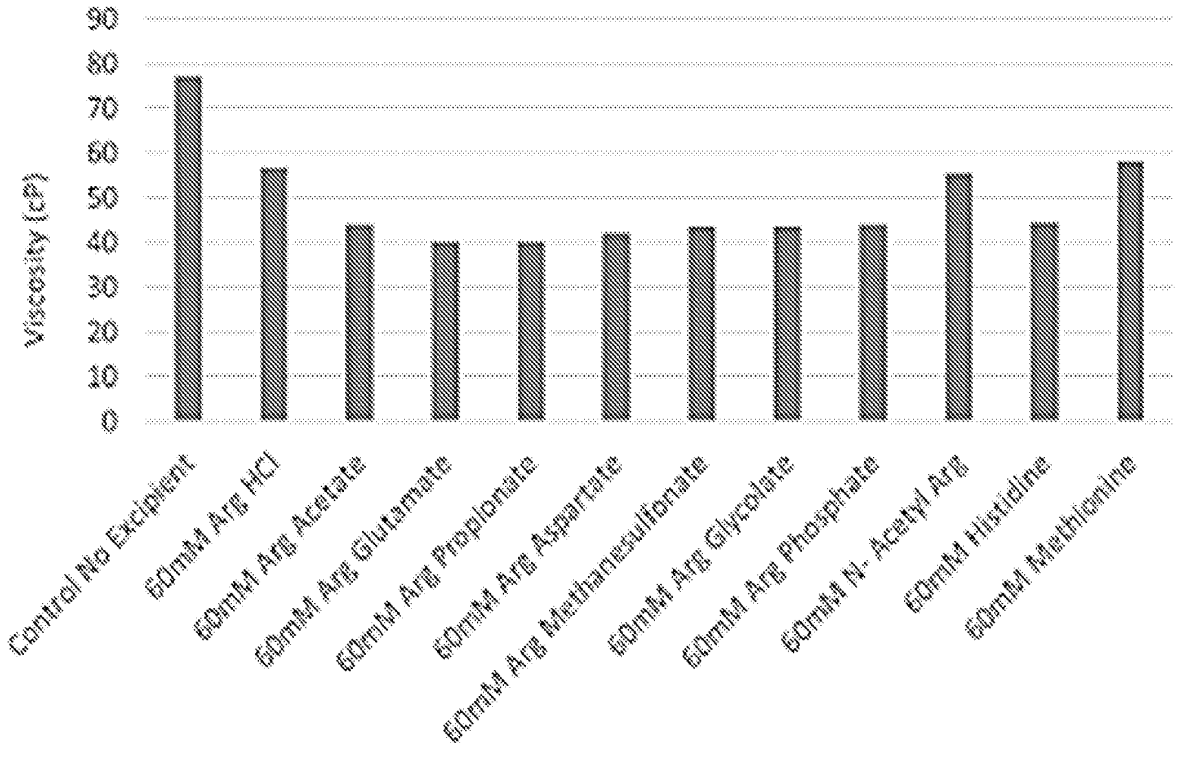

Viscosity (cP)
90
80
70
60
50
40
30
20
10
0
Control No Excipient
60mM Arg HCl
60mM Arg Acetate
60mM Arg Glutamate
60mM Arg Propionate
60mM Arg Aspartate
60mM Arg Methanesulfonate
60mM Arg Glycolate
60mM Arg Phosphate
60mM N- Acetyl Arg
60mM Histidine
60mM Methionine

FIG. 7

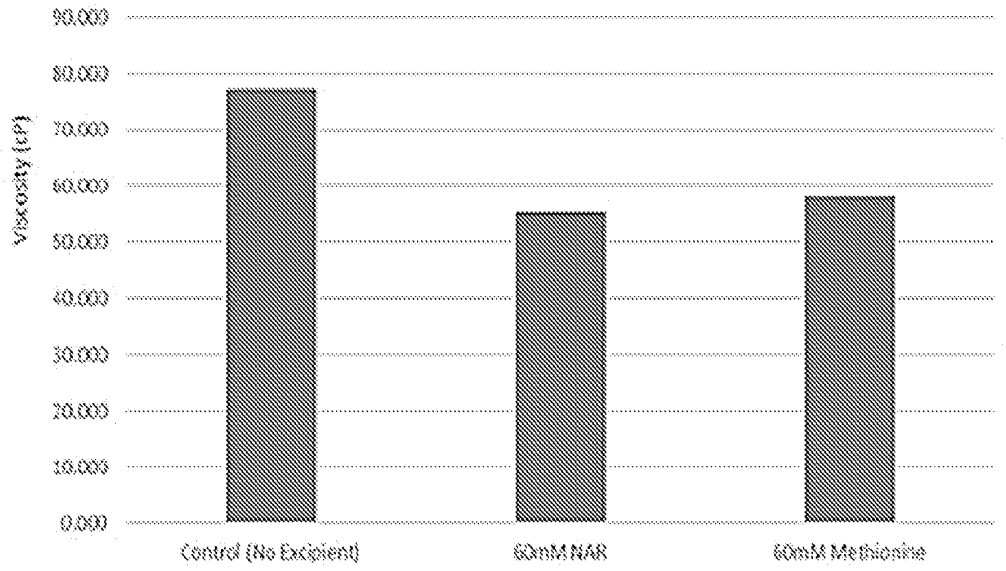


FIG. 8

		180 mg/mL Samples			210 mg/mL Samples		
		Conc (mg/mL)	Viscosity (cP)	pH	Conc (mg/mL)	Viscosity (cP)	pH
ArgGlu	150mM ArgGlu	188.3	30.0	5.3	215.6	59.0	5.3
	100mM ArgGlu + 100mM NAR	185.7	27.0	5.1	212.8	55.8	5.2
	100mM ArgGlu + 100mM Met	183.8	27.0	5.2	216.3	62.3	5.2
	75mM ArgGlu + 150mM NAR	184.5	28.3	5.2	213.7	62.2	5.2
	75mM ArgGlu + 150mM Met	184.1	25.1	5.2	211.1	55.2	5.2
	100mM ArgGlu + 50mM NAR + 50mM Met	185.3	27.7	5.1	215.8	64.5	5.2
CaGlu	100mM CaGlu	188.0	24.7	5.1	217.2	57.3	5.2
	67mM CaGlu + 100mM NAR	187.7	24.2	5.2	213.9	51.0	5.2
	67mM CaGlu + 100mM Met	186.4	23.4	5.2	213.6	49.3	5.2
	50mM CaGlu + 150mM NAR	181.2	24.1	5.3	212.7	57.8	5.3
	50mM CaGlu + 150mM Met	184.5	22.5	5.1	212.5	48.3	5.1
	67mM CaGlu + 50mM NAR + 50mM Met	184.3	23.6	5.1	213.0	53.2	5.2

FIG. 9A

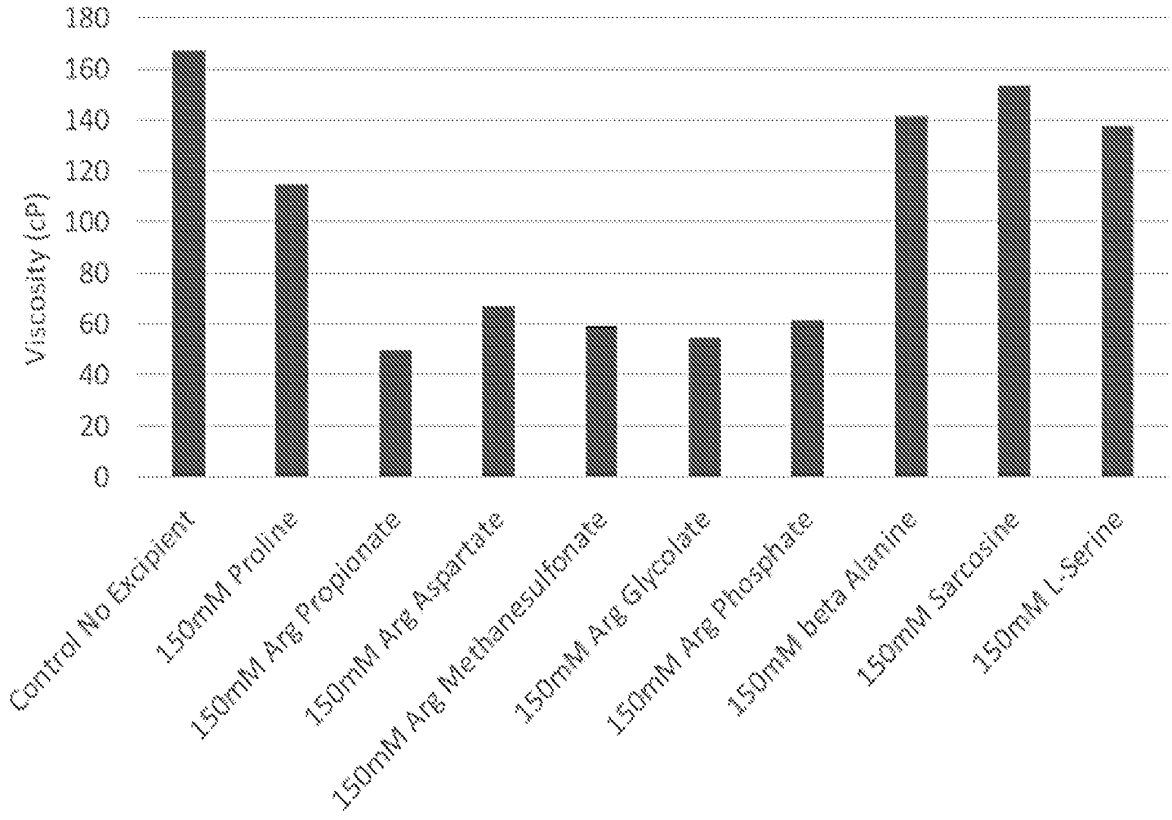

Viscosity (cP)
180
160
140
120
100
80
60
40
20
0
Control No Excipient
150mM Proline
150mM Arg Propionate
150mM Arg Aspartate
150mM Arg Methanesulfonate
150mM Arg Glycolate
150mM Arg Phosphate
150mM beta Alanine
150mM Sarcosine
150mM L-Serine

FIG. 9B

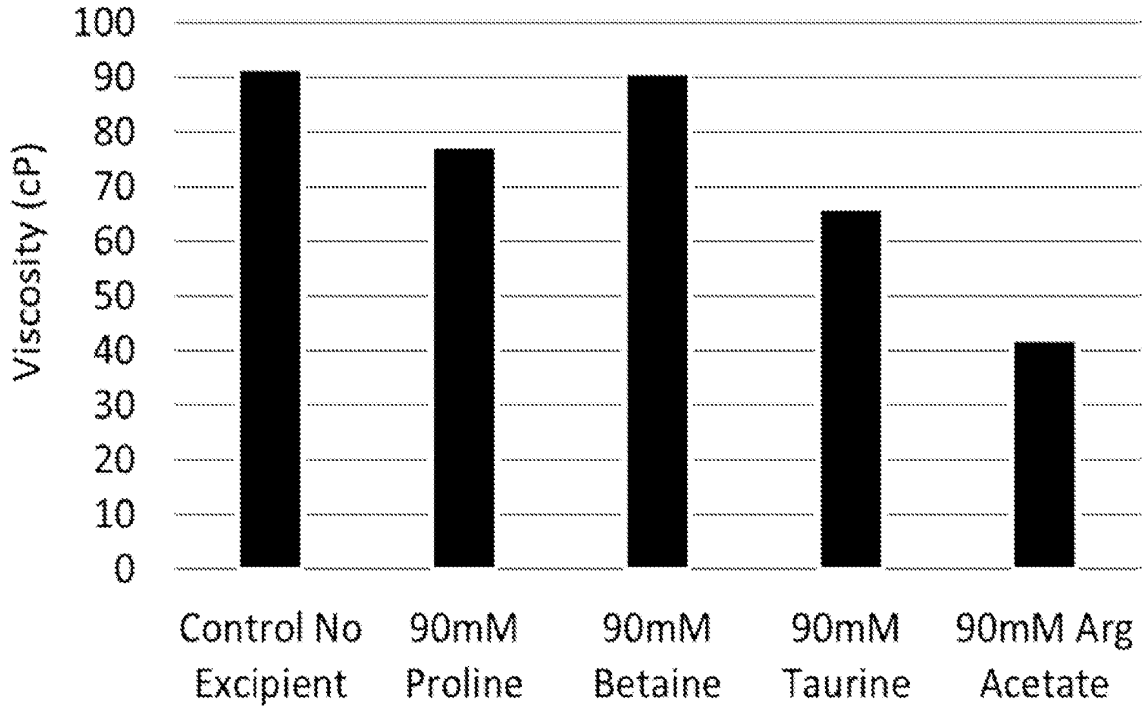

Viscosity (cP)
100
90
80
70
60
50
40
30
20
10
0
Control No Excipient
90mM Proline
90mM Betaine
90mM Taurine
90mM Arg Acetate

FIG. 10

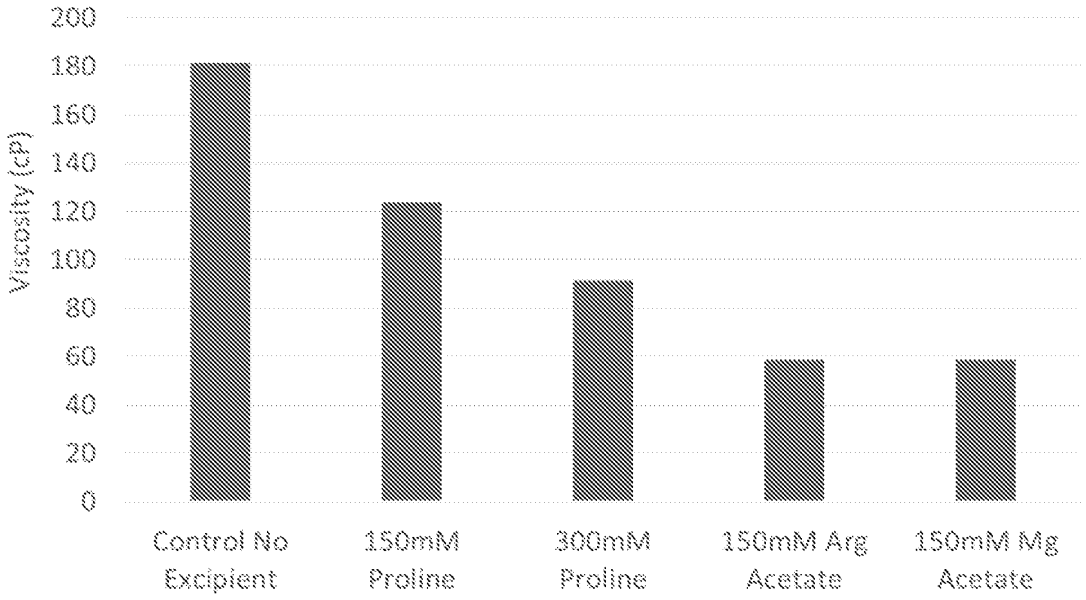

Viscosity (cP)
200
180
160
140
120
100
80
60
40
20
0
Control No Excipient
150mM Proline
300mM Proline
150mM Arg Acetate
150mM Mg Acetate

FIG. 11

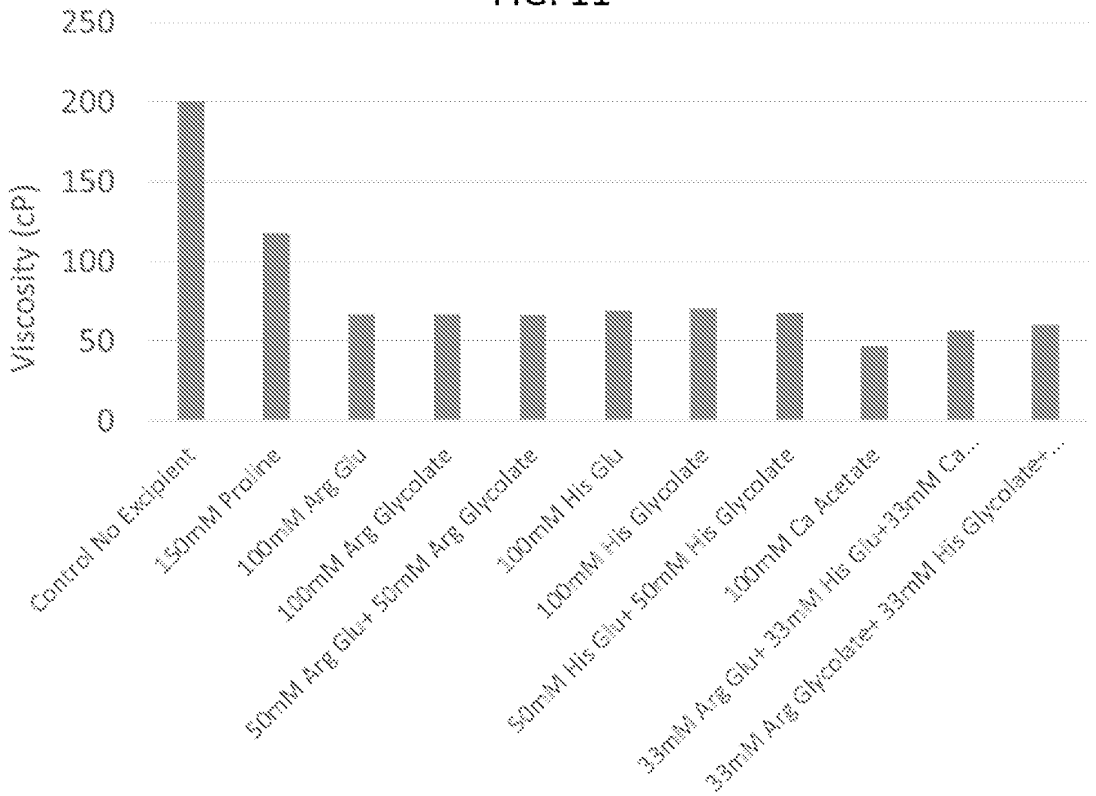

Viscosity (cP)
250
200
150
100
50
0
Control No Excipient
150mM Proline
100mM Arg Glu
100mM Arg Glycolate
50mM Arg Glu+ 50mM Arg Glycolate
100mM His Glu
100mM His Glycolate
50mM His Glu+ 50mM His Glycolate
100mM Ca Acetate
33mM Arg Glu+ 33mM His Glu+33mM Ca...
33mM Arg Glycolate+ 33mM His Glycolate+...

FIG. 12

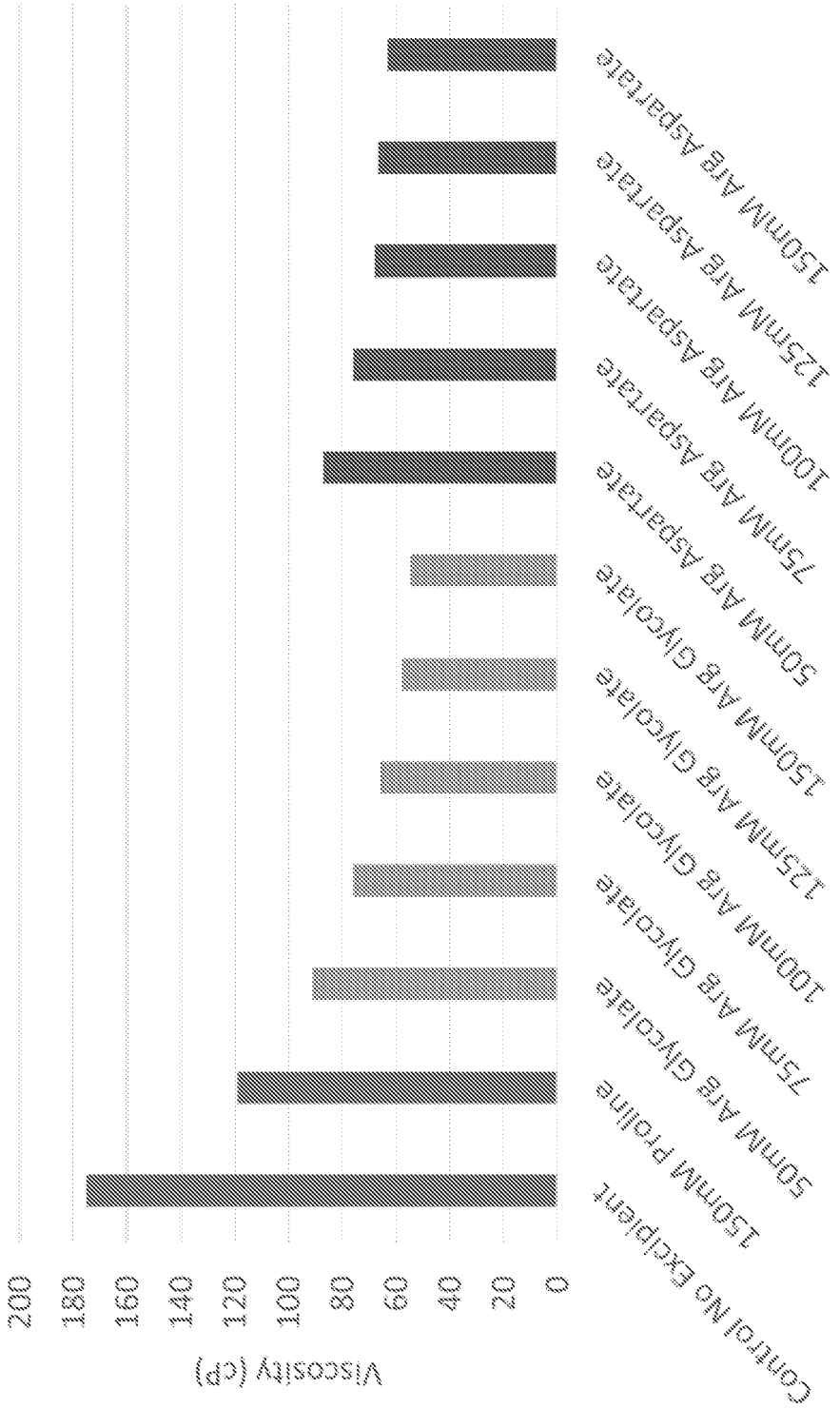

Control No Excipient
150mM proline
50mM ARB Glycolate
75mM ARB Glycolate
100mM ARB Glycolate
125mM ARB Glycolate
150mM ARB Glycolate
50mM ARB Glycolate
75mM ARB Aspartate
100mM ARB Aspartate
125mM ARB Aspartate
150mM ARB Aspartate
Viscosity (cP)
0
20
40
60
80
100
120
140
160
180
200

FIG. 13A

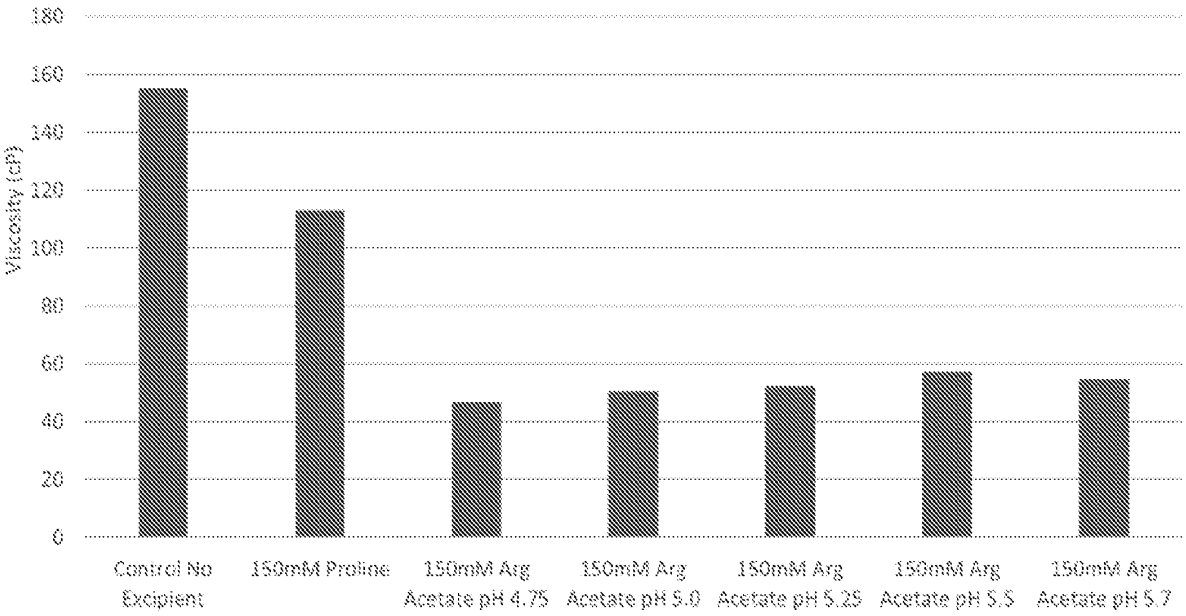


FIG. 13B

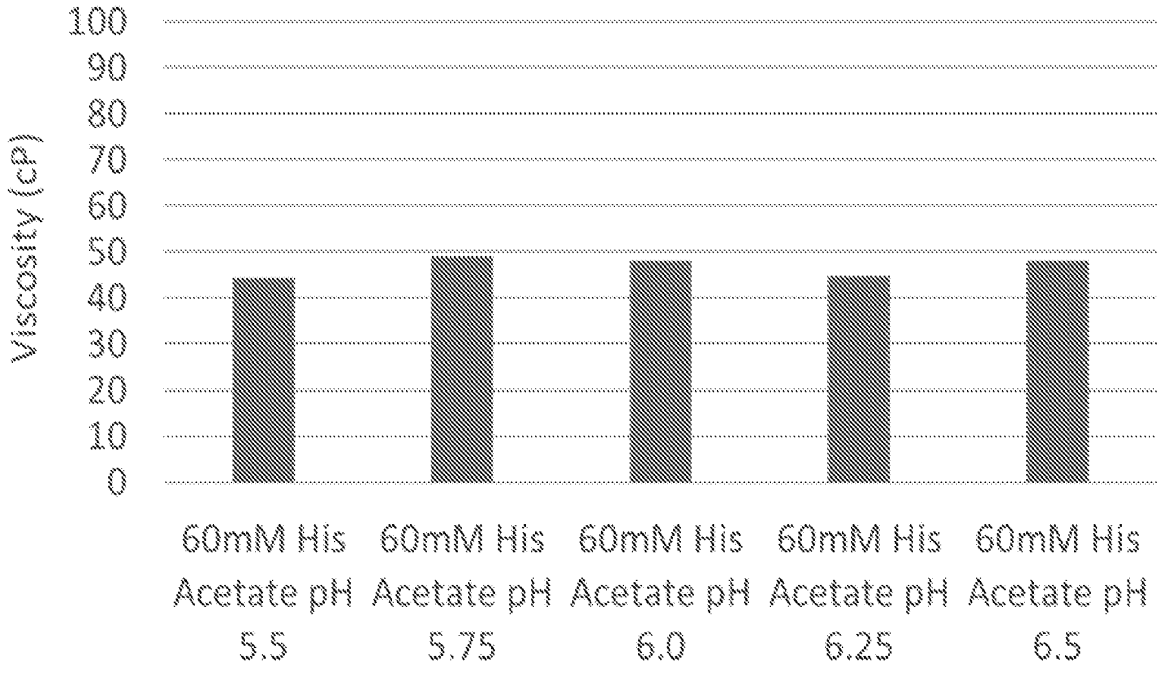


FIG. 14

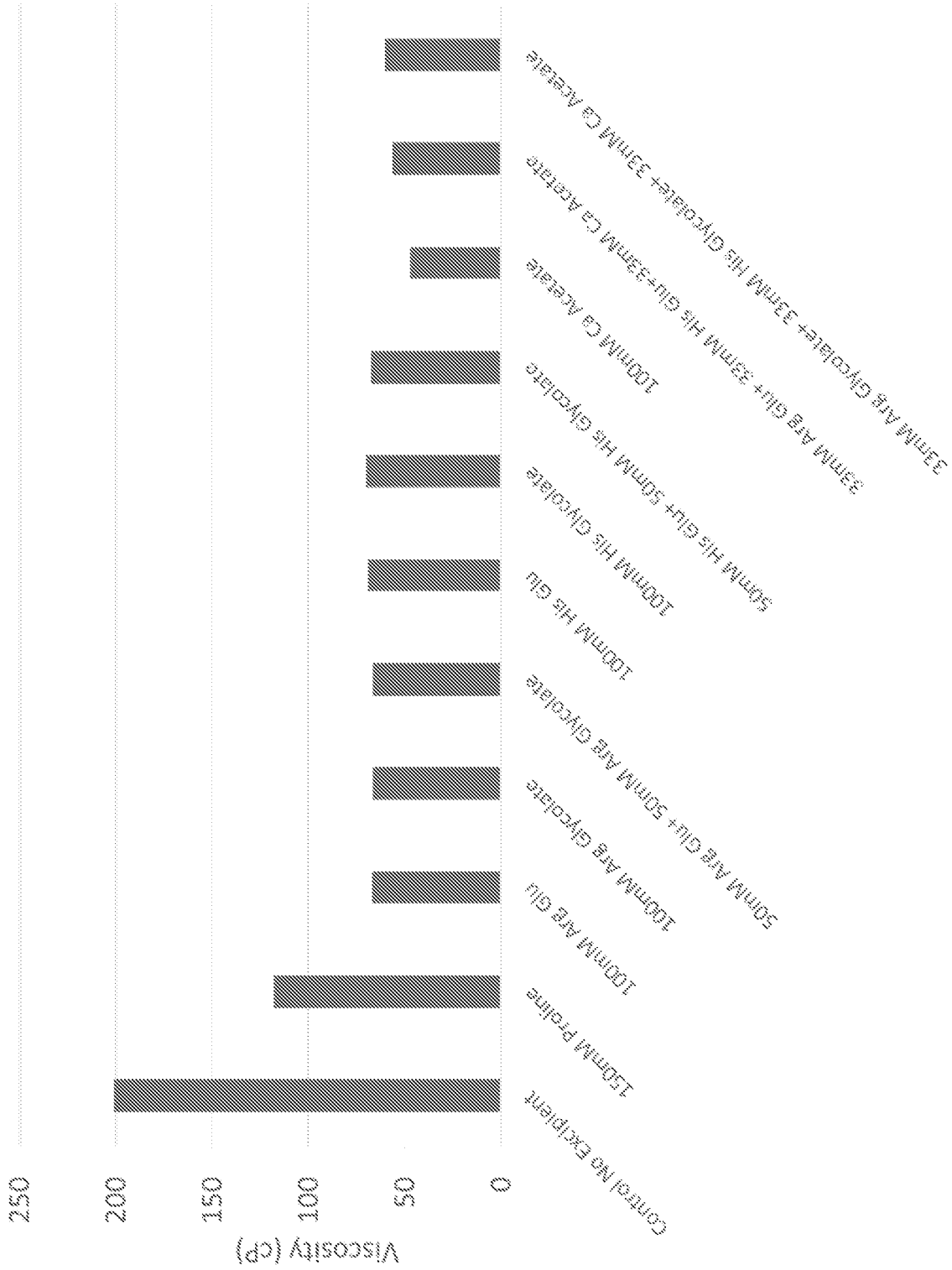

Control No Excipient
150mM proline
100mM Arg Glu
100mM Arg Glycolate
50mM Arg Glu+ 50mM Arg Glycolate
100mM His Glu
100mM His Glycolate
50mM His Glu+ 50mM His Glycolate
100mM Ca Acetate
33mM Arg Glu+ 33mM His Glu+33mM Ca Acetate
33mM Arg Glycolate+ 33mM His Glycolate+ 33mM Ca Acetate
0
50
100
150
200
250
Viscosity (cP)

FIG. 15A

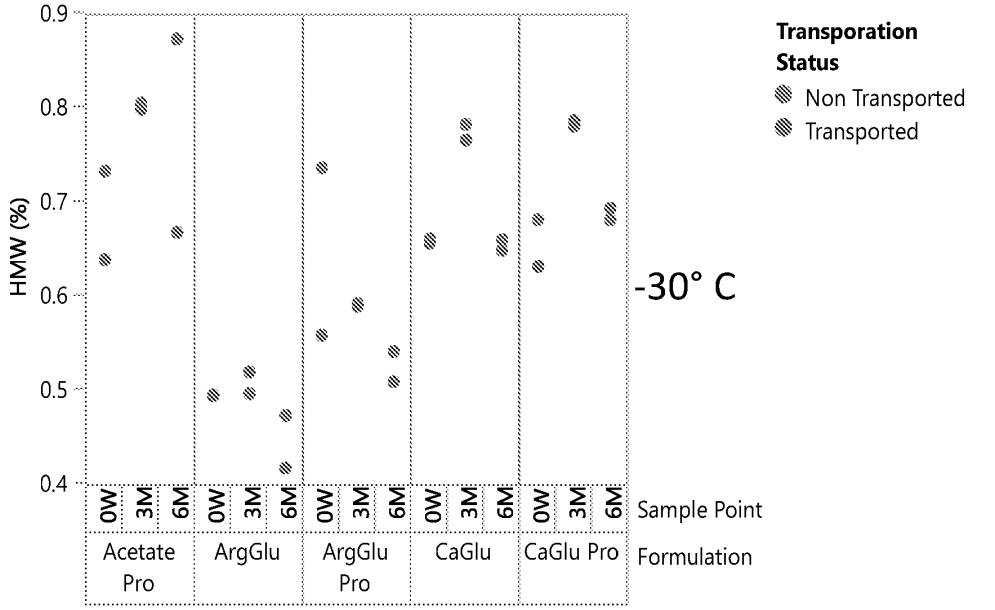


FIG. 15B

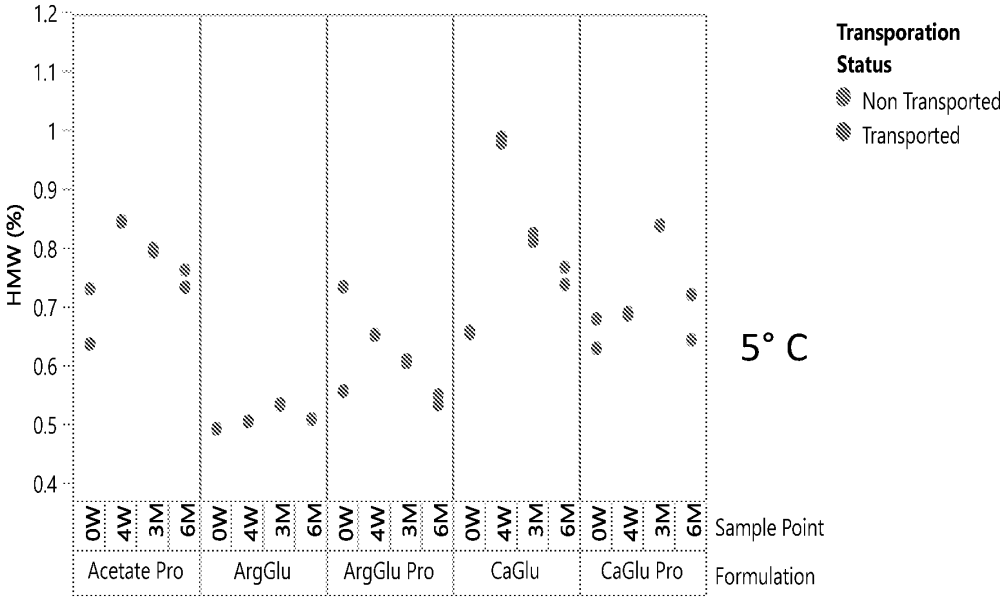


FIG. 15C

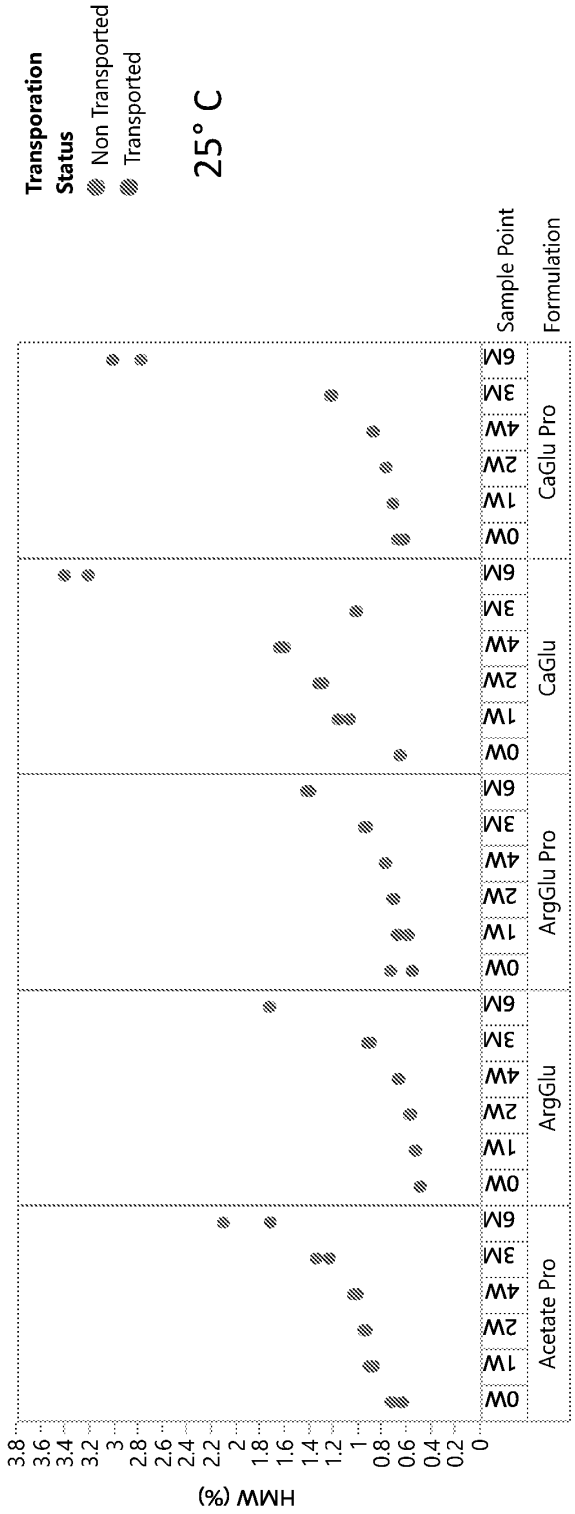

Transporation Status
Non Transported
Transported
25° C
HMW (%)
0
0.2
0.4
0.6
0.8
1
1.2
1.4
1.6
1.8
2
2.2
2.4
2.6
2.8
3
3.2
3.4
3.6
3.8
Sample Point
Formulation
0W
1W
2W
4W
3M
6M
Acetate Pro
ArgGlu
ArgGlu Pro
CaGlu
CaGlu Pro

FIG. 15D

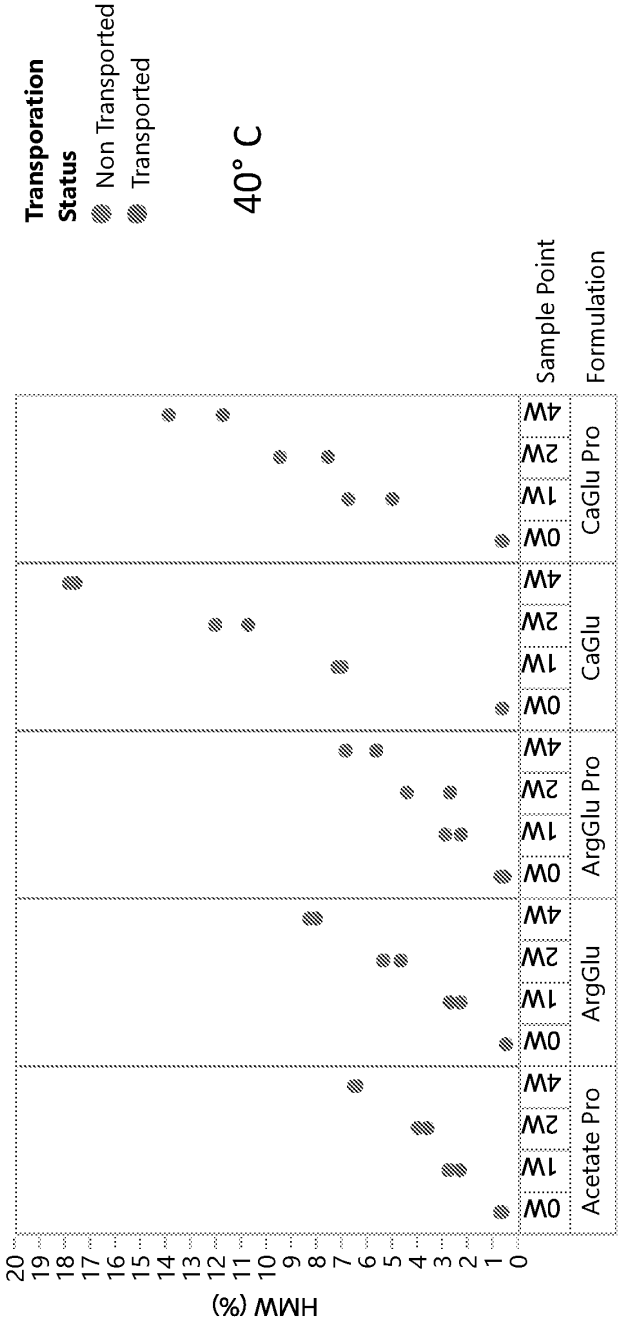
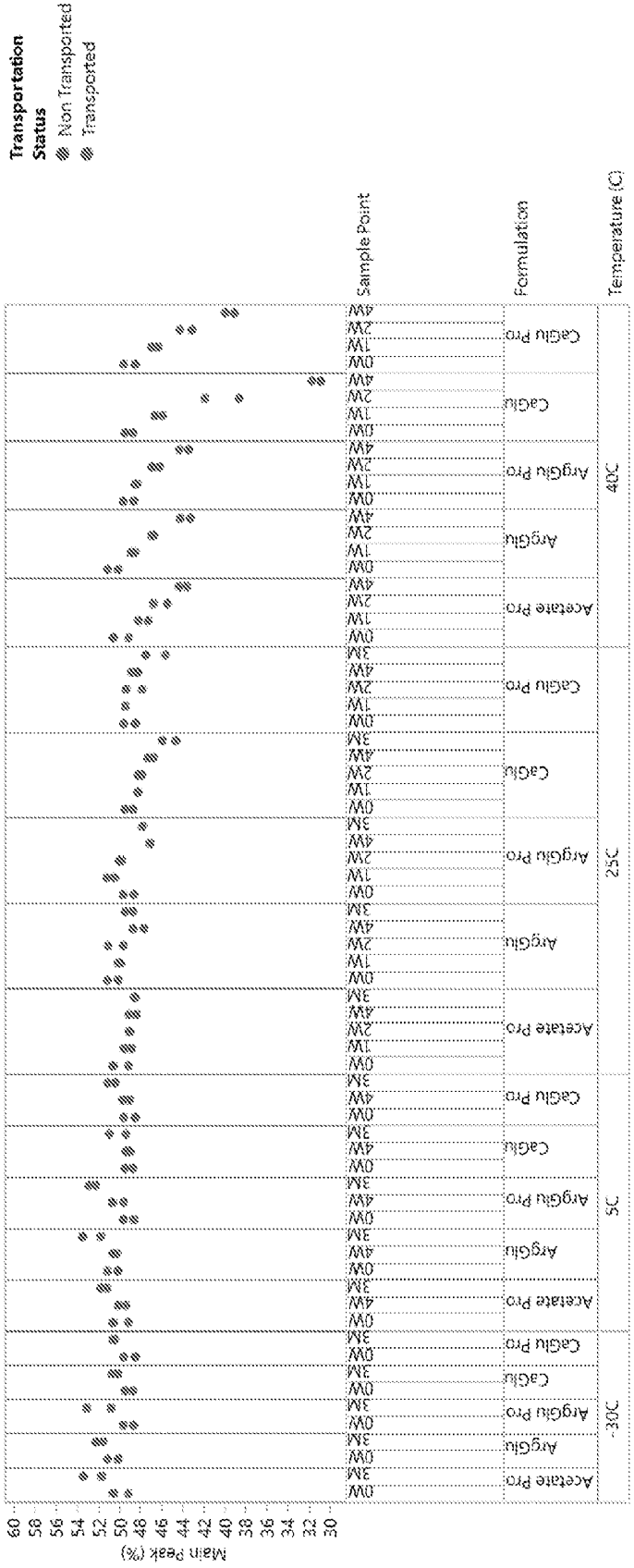

Transporation Status
Non Transported
Transported
40° C
HMW (%)
0
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
Formulation
Sample Point
Acetate Pro
ArgGlu
ArgGlu Pro
CaGlu
CaGlu Pro
0W
1W
2W
4W

FIG. 16



CEX Main Peak

FIG. 17

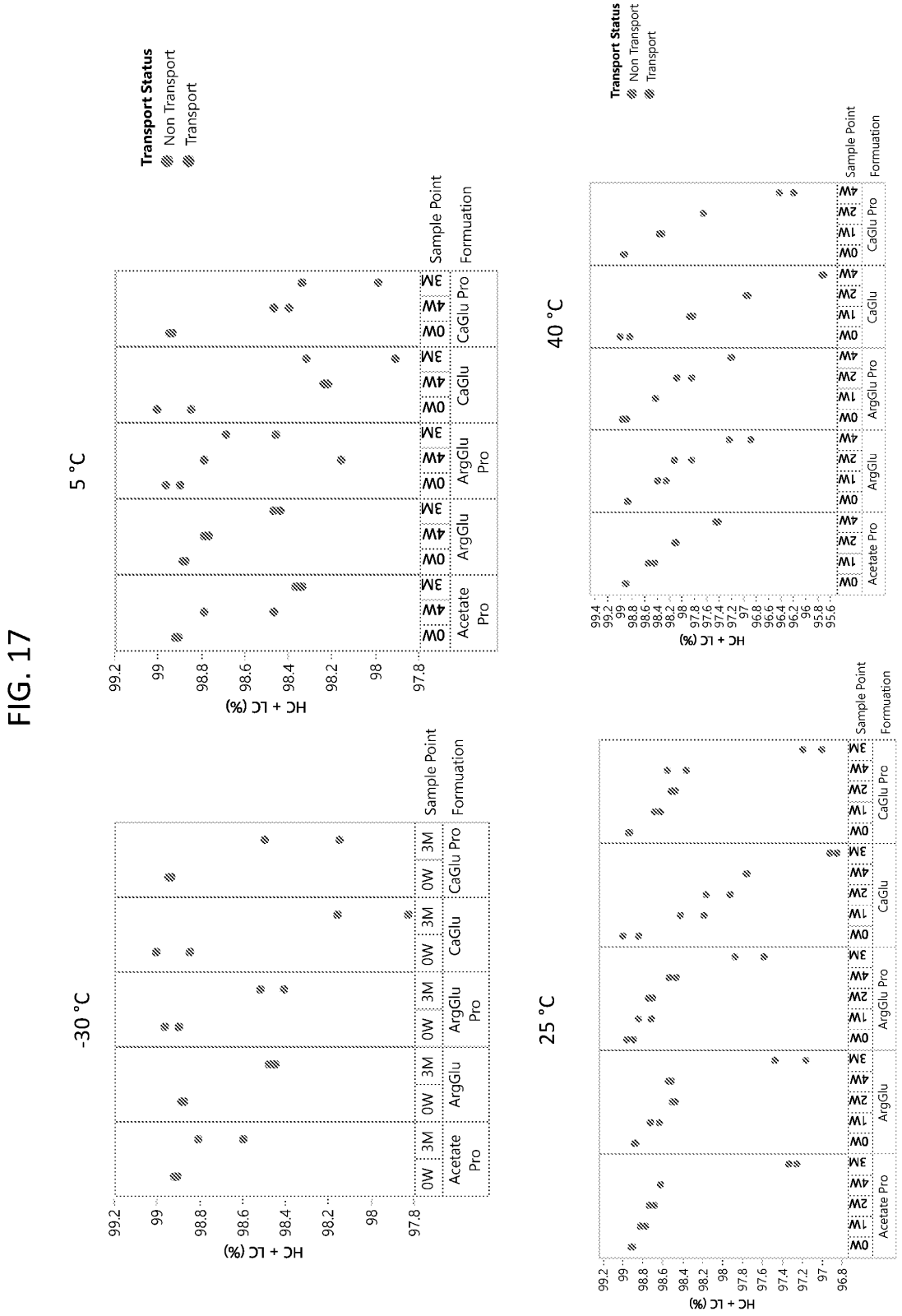
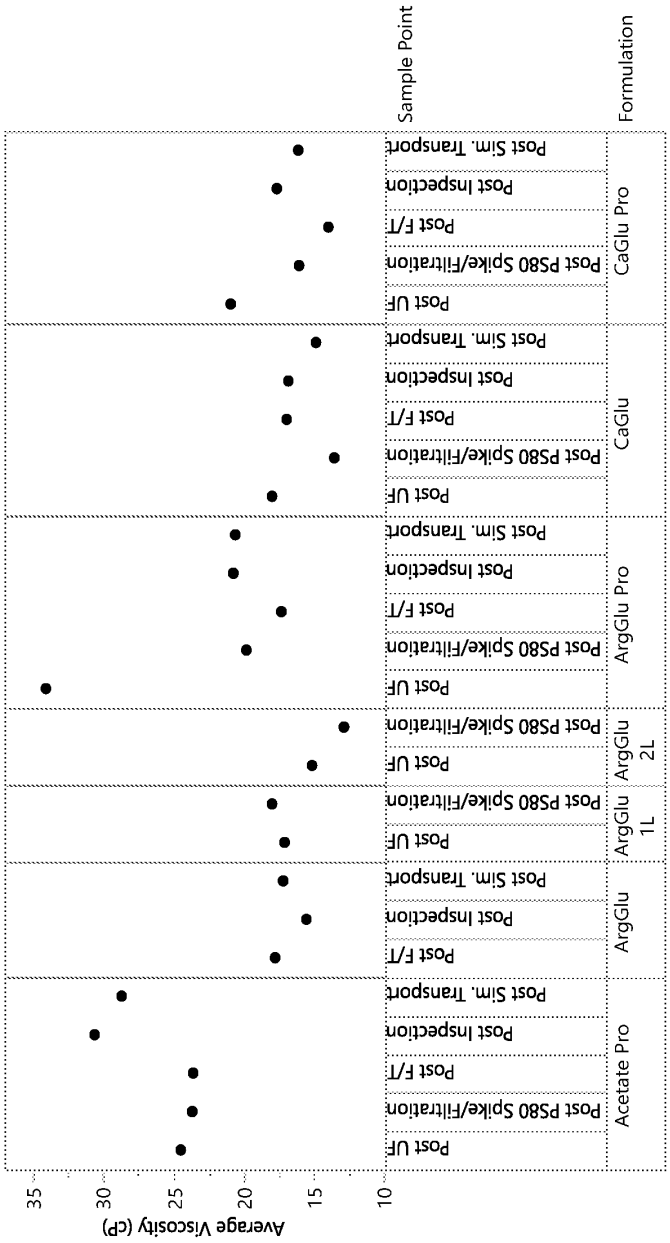

-30 °C
5 °C
25 °C
40 °C
Transport Status
Non Transport
Transport
HC + LC (%)
Sample Point
Formuation
Acetate Pro
ArgGlu
ArgGlu Pro
CaGlu
CaGlu Pro
0W
1W
2W
4W
0M
3M

FIG. 18


Average Viscosity (cP)
35
30
25
20
15
10
Sample Point
Post UF
Post PS80 Spike/Filtration
Post F/T
Post Inspection
Post Sim. Transport
Formulation
Acetate Pro
ArgGlu
ArgGlu 1L
ArgGlu 2L
ArgGlu Pro
CaGlu
CaGlu Pro